

FCS06 - SOP for Reviewing Reports

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1. Scope

- 1.1. These practices apply to Forensic Chemistry Analyst within the Unit who performs technical review of data that will be submitted externally or performed as internal validations, as well as any externally provided conclusions or administrative reviews of analytical reports.

2. Background

- 2.1. To establish practices within the Forensic Chemistry Unit (FCU) of the Public Health Laboratory (PHL) Division in the Washington, D.C., Department of Forensic Sciences (DFS) for reviewing *Report of Examination / Discontinuation of Analysis / Amended Report of Analysis / Supplemental Report of Examination* or other results to be submitted to an external contributor or for purposes of a Proficiency Test. This is in conformance to the *FCS02 – SOP for General Laboratory Procedures for FCU* and the *FCU Quality Assurance Manual*.
- 2.2. Responsibilities
 - 2.2.1. The Unit Manager shall:
 - 2.2.1.1. Notify Customer of capabilities of the FCU, when appropriate.
 - 2.2.1.2. Ensure adequacy of test performed to meet Customer's requirements.
 - 2.2.1.3. Perform Administrative Review of analytical report.

2.2.1.4. Approve any minor deviations from the accepted SOP.

2.2.2. The Analyst shall:

2.2.2.1. Obtain permission to perform analysis by Unit Manager prior to initiating analysis.

2.2.2.2. Perform the analysis as described in each Unit SOP.

2.2.2.3. Perform a Technical Review of the analytical report.

2.2.2.4. Ensure all technical documents have the Analyst's initials and date of analysis performed.

2.2.2.5. Report any nonconformities to the Unit Manager or designee.

2.2.3. The Technical Reviewer shall:

2.2.3.1. Be an employee or contract employee currently qualified in the methodology being reviewed.

2.2.3.2. Not be the originator of the analysis being reviewed.

2.2.3.3. Ensure that appropriate analyses have been performed.

2.2.3.4. Review and approve any identifications, conclusions, or associations, and ensure they are documented.

2.2.3.5. Ensure that conclusions are supported in the technical records, and that these conclusions are within the scope of the discipline.

2.2.3.6. Document the Technical Review in a technical and administrative review form.

2.2.4. The Administrative Reviewer shall:

2.2.4.1. Ensure the analytical report is clear, concise and complete.

2.2.4.2. Ensure the report does not contain any spelling or grammatical errors.

2.2.4.3. Ensure conformance to FCS02 – SOP for General Laboratory Procedures for FCU.

2.2.4.4. Verify that the necessary technical review has been performed and documented in the FCU case file.

2.2.4.5. Document the administrative review.

3. Safety

3.1. Personnel should refer to the appropriate SDS for solvents and reagents used during analysis for any specific safety requirements. For a complete review of required Health and Safety regulations of the PHL, see the *DFS Health and Safety Manual*.

4. Materials Required

4.1. Not applicable.

5. Standards and Controls

5.1. Not Applicable.

6. Calibration

6.1. Not Applicable.

7. Procedures

7.1. General Requirements

- 7.1.1. After completion of an analysis and prior to sample or evidence return or destruction and prior to submitting the results to the Customer, all analytical reports are to be technically and administratively reviewed by qualified personnel. The technical report and supporting documentation (notes, charts, photographs, etc.) shall undergo a Technical Review to ensure that the conclusions are supported and documented by the data.
- 7.1.2. Each identification, conclusion and/or association shall be confirmed by a review of the data by a Technical Reviewer.
- 7.1.3. All Report of Examination / Discontinuation of Analysis / Amended Report of Analysis / Supplemental Report of Examination sent to a Customer shall undergo a Technical Review prior to an Administrative Review.
- 7.1.4. All Report of Examination / Discontinuation of Analysis / Amended Report of Analysis / Supplemental Report of Examination shall undergo an Administrative Review prior to being submitted to the Customer.
- 7.1.5. Unit employees may not administratively or technically Review their own work.
- 7.1.6. Technical and Administrative Review may be performed by the same person.
- 7.1.7. The Technical Review must be performed by an individual who is competent to perform case analysis for FCU.
- 7.1.8. The individual performing the Administrative Review does not need to be competent in performing case analysis for FCU.

7.2. Technical Review

- 7.2.1. Technical Reviews shall be performed by a peer or supervisor technically competent in the FCU SOP used. If the analytical report is performed by the Unit Manager, then a competent Analyst may perform a Technical Review.
- 7.2.2. The Technical Review shall ensure that sufficient documentation is present such that another qualified analyst other than the one who performed the analysis under similar conditions.
- 7.2.3. The Technical Review shall include:
 - 7.2.3.1. Ensuring the appropriate analyses have been performed,
 - 7.2.3.2. Ensuring the accuracy of the analyst's calculations (when appropriate),
 - 7.2.3.3. Ensuring that the analyst's conclusions / critical findings are consistent with the documented data and within the scope of the SOP,
 - 7.2.3.4. Ensuring there is sufficient supporting documentation,
 - 7.2.3.5. Ensuring conclusions, identifications and / or associations are documented.
 - 7.2.3.6. Upon completion of the Technical Review, the Technical Reviewer shall document the review by signing and dating the review materials and forward the report to the individual performing the Administrative Review.

7.3. Administrative Review

- 7.3.1. Administrative Reviews are to be conducted by the Unit Manager, or designee.
- 7.3.2. An Administrative Review shall be performed on all Report of Examination / Discontinuation of Analysis / Amended Report of Analysis / Supplemental Report of Examination generated by FCU personnel. The review shall ensure:
 - 7.3.2.1. The report is clear, concise, accurate and complete.
 - 7.3.2.2. All records are free of spelling errors and/or grammatical errors.
 - 7.3.2.3. The Report of Examination / Discontinuation of Analysis / Amended Report of Analysis / Supplemental Report of Examination conforms to FCU quality practices.
 - 7.3.2.4. A Technical Review has been completed and documented.
 - 7.3.2.5. All data transfers that occur that are not part of a validated electronic process are checked.
 - 7.3.2.6. Upon completion of the Administrative Review, the Reviewer

shall document the review by signing and dating the review materials.

7.4. Conflict Resolution

7.4.1. There may be instances when the reviewer and individual who performed the analysis cannot resolve significant differences in results obtained or conclusions drawn prior to issuing the final report. If, after discussion and review the disagreement remains, a third, technically competent individual (if available) must be consulted. If disagreement remains, the Reviewer shall notify the FCU Manager. The FCU Manager shall make a decision and document the resolution within the report.

7.4.1.1. If the FCU Manager decides that the difference is significant or warranted for inclusion in the final report, then a note shall be made to include said minority opinion and included as part of the final report.

7.4.2. The FCU Manager may defer the decision to the PHL Director. The decision made by the FCU Manager or PHL Director shall stand as the final conclusion for the report. The analyst issuing the *Report of Examination / Discontinuation of Analysis / Amended Report of Analysis / Supplemental Report of Examination* shall be responsible for adhering to the decision when issuing the report.

8. Sampling

8.1. Not applicable

9. Calculations

9.1. Not applicable

10. Uncertainty of Measurement

10.1. When quantitative results are obtained, and the significance of the value may impact the report, the uncertainty of measurement must be determined.

11. Limitations

11.1. These practices pertain solely to the FCU laboratory.

12. Documentation

12.1. Documentation or confirmation of an identification or association

12.2. Report of Examination / Discontinuation of Analysis / Amended

Report of Analysis / Supplemental Report of Examination

12.3. Record of technical / administrative review

13. References

13.1. FCU *Quality Assurance Manual*, (current version)

13.2. FCU Method SOPs, (current revisions).

13.3. FCU Training Manual, (current revision).